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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,809	12/19/2001	Nancy L. Craig	35789/241825 (5789-3A)	3573

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11/03/2003

Gregory D. Williams
New England Biolabs, Inc.
32 Tozer Road
Beverly, MA 01915

EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,809	CRAIG, NANCY L.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>1003</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 26-30 are directed to an invention that is independent or distinct from the invention originally claimed, and which received an Office Action requiring an election of distinct inventions. However, in a previous telephone conversation with Applicant's attorney/agent, the examiner agreed to consider claims that were not previously presented prior to the issuance of the Election/Restriction requirement, provided that the newly added claims were drawn to a single invention for purposes of compact prosecution (see the attached Interview Summary). Upon a review of the claims, the examiner finds that the claims are drawn to a single distinct invention, and will treat these claims as being elected without traverse.

Claims 26-30 are pending and under consideration in the instant application. Claims 1-26 have been cancelled in response to the Election/Restriction requirement.

Priority

Applicant's claim for domestic priority to US Application No. 60/037,955 under 35 U.S.C. 119(e) is acknowledged. Applicant's claim for domestic priority to US Application No. 09/027,169 (Now US Patent No. 6,420,524) under 35 U.S.C. 120 is acknowledged.

However, concerning the claims and the inclusion of the limitation processing into a form "suitable for transforming a host cell," priority is not granted because neither priority application contains a description of what is "suitable" for transformation (in fact, the word "suitable" appears nowhere in either specification). Similarly, regarding claim 27, particularly the limitation "occurs in the absence of a phenol extraction step," priority is not granted to these

applications because the negative limitation is not present in either of the applications. (see also the rejections under 35 USC 112, first paragraph, New Matter).

Information Disclosure Statement

The information disclosure statement filed December 19, 2001 has been considered, and a signed and initialed copy of the form PTO-1449 is attached to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Specifically, the claims are directed to a method of processing something (see rejections under 35 USC § 112, second paragraph) into a form "suitable for transforming a host cell," where this limitation as not support in the instant specification. The limitation "suitable for transforming a host cell" is not present anywhere in the specification as originally filed, therefore it is unclear what forms are suitable for transforming a host cell.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Specifically, claim 27 recites a negative limitation that is not supported in the instant specification, that limitation being that the “processing occurs in the absence of a phenol extraction step.” There is nothing in the specification to indicate that any of the disclosed methods occur in the absence of a phenol extraction step. The fact that the method step does not include a phenol extraction step is not sufficient to establish that such a step *must not* be included; such a limitation requires specific instruction. As such, this limitation constitutes new matter.

Claims 26-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of subjecting DNA to a temperature greater than 75°C in order to disrupt a complex of target DNA, donor DNA and a transposase in an *in vitro* transposition reaction, does not reasonably provide enablement for a method of subjecting DNA to a temperature greater than 65°C in order to disrupt a complex of target DNA, donor DNA and a transposase in an *in vitro* transposition reaction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is a method of disrupting a complex between a transposase, a target DNA molecule and a donor DNA molecule by applying heat treatment, thereby putting the DNA into a form for transforming host cells. In the specification (see pages 99-103) it is taught that heat treatment of 75°C is adequate for the disruption of the complex, but that heat treatment at 65°C is inadequate for the disruption of the complex.

Scope of the invention. The scope of the invention is very broad, claiming the ability to disrupt the transposase/DNA donor molecule/DNA target molecule complex at a number of temperatures below the temperature that has been shown to be adequate.

State of the art and Level of skill in the art. The state of the art is silent with regard to the use of heat treatment to put complexes comprising a transposase, a DNA donor molecule and a DNA target molecule into a form for transforming into host cells. There is no indication as to what temperatures would be suitable for performing such a method, thus the skilled artisan would be required to rely solely on the instant specification in order to use the claimed invention.

Number of working examples and Guidance provided by applicant. The instant specification describes two scenarios: one where a heating a complex comprising a transposase, a

DNA donor molecule and a DNA target molecule at a temperature of 75°C is adequate to put a DNA molecule resulting from an in vitro transposition reaction into a form for transforming host cells; one where heating a complex comprising a transposase, a DNA donor molecule and a DNA target molecule at a temperature of 65°C is inadequate to put a DNA molecule resulting from an in vitro transposition reaction into a form for transforming host cells. Armed with these teachings, the skilled artisan could only come to the conclusion that heating at a temperature of 75°C would be sufficient to put a DNA molecule resulting from an in vitro transposition reaction into a form for transforming host cells; the skilled artisan would be unable to discern what temperatures between 65°C and 75°C would also be adequate from these teachings. Thus, the instant claims are not enabled for the broad scope that is indicated.

Unpredictability of the art and Amount of experimentation required. The art is unpredictable because it would require empirical experimentation to determine what range of temperatures would be useful in the claimed method. In order to practice the full scope of the claimed invention, the skilled artisan would have to determine the minimum temperature at which the claimed method could be used by trial and error experimentation. The instant claims are directed to embodiments that include a temperature of 65.000001°C, which is greater than 65°C, and all temperatures above that. There is no demonstration that this temperature, or that any temperature between 65°C and 75°C (i.e., 66°C, 67°C, etc.) could be used in the claimed method. There is only a demonstration that a temperature of 75°C or greater is sufficient for the claimed method. In essence, there is a grey area between 65°C and 75°C where neither the instant specification nor the skilled artisan is apprised of the ability to disrupt the the transposase/DNA donor molecule/DNA target molecule complex. The fact that no temperature

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below 75°C has been demonstrated for use in the claimed method, yet temperatures below this are claimed, represents an invitation to experiment; the claims invite the skilled artisan to determine at what point the method becomes inoperable. As such, the full scope of the invention is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is rejected because it is unclear if the claim is complete, because the claim contains no period. As a result, the metes and bounds of the claim are indefinite because it is unclear if the claim comprises more steps.

Claim 26 reads "A method of processing into a form suitable for transforming a host cell, a DNA product..." It is unclear if the host cell is being processed into a form suitable for being transformed, or if the DNA product is being processed into a form suitable for being transformed into a host cell. It would be remedial to indicate "A method of processing a DNA product from an in vitro transposition reaction into a form for transforming a host cell..." if the method is directed to such a process.

The term "suitable" in claim 26 is a relative term which renders the claim indefinite. The term "suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably

apprised of the scope of the invention. It is unclear what constitutes a "suitable" DNA product or host cell, therefore the metes and bonds of the claim are indefinite.

The term "effective" in claims 26 and 28 is a relative term which renders the claim indefinite. The term "effective" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what constitutes an "effective" amount of time, therefore the metes and bounds of the claim are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 26-30 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Specifically, the inventive entity on the instant application is Nancy Craig. However, in the response to the Election/Restriction requirement, applicant has indicated that it is necessary to amend the inventive entity to include Elisabeth Raleigh and Fiona Stewart as inventors (see page 3, paragraph 2 of the response). Thus the claimed subject matter is the invention of an entity that is distinct from that currently indicated in the application.

Allowable Subject Matter

No claims are allowable.

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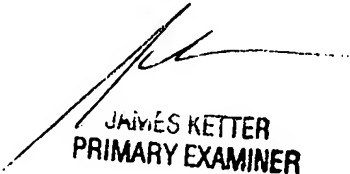
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
AU 1636



JAMES KETTER
PRIMARY EXAMINER